

A Risk-Based Revalidation Approach For Medical Devices



Yeong-Lin Chen

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ABSTRACT Process validation approach for medical device industry is diverse, which is due to a wide range of technologies and applications. Process revalidation approach is even more uncertain while compared with initial validation. In medical device industry, manufacturing change-induced revalidation is validation professionals' everyday activity so it will be burdensome if not efficiently managed. This article proposes a risk-based revalidation approach with a simple and pragmatic risk assessment method for mechanical-type medical device manufacturing. Use the risk assessment output in conjunction...

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